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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,236	03/04/2002	Christine Dingivan	10271-053	7180

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EXAMINER
GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/091,236	DINGIVAN ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) *7,8,12-17,19-21,25-27,32-42,53,55-57,61 and 63-70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9-11,18,22-24,28-31,43-52,54,58-60 and 62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____:
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 10/13/06, has been entered.
Claims 2, 4, 6, 11, 29-30, 43-52, 54 and 58-61 have been amended.

Applicant's election of Group I and to prosecute the species wherein the alphavbeta3 antagonist is VITAXIN / anti-alphavbeta3 antibody and the TNF-alpha antagonist is REMICADE / anti-TNF-alpha antibody in the Reply, filed 12/1205 and the disease "rheumatoid arthritis" in the Reply, filed 3/31/06, has been acknowledged.

As noted previously, given that applicant does not admit or provide evidence the species are obvious variants, the species requirement was maintained for the reasons of record.

Also, as noted previously, upon reconsideration of the elected species "rheumatoid arthritis" in the context of the claimed invention and the prior art search, the examiner has extended the search in the context of treating rheumatoid arthritis with "anti-alphavbeta3 antibodies", as exemplified by the "LM609 / Vitaxin antibody" in combination with "anti-TNFα antibodies", as exemplified by the cA2 / Remicade / infliximab antibody and further in conjunction with standard therapy of treating arthritis with "methotrexate" and "non-steroidal anti-inflammatory drugs" in the interest of compact prosecution.

Claims 1-6, 9-11, 18, 22-24, 28-31, 43-52, 54, 58-60 and 62 are under consideration in the instant application, as they read on the elected invention / species, that is, "LM609 / Vitaxin antibody" in combination with "anti-TNFα antibodies", as exemplified by the cA2 / Remicade / infliximab antibody and further in conjunction with standard therapy of treating arthritis with "methotrexate" and "non-steroidal anti-inflammatory drugs".

However, claims 7-8, 12-17, 19-21, 25-27, 32-42, 53, 55-57, 61 and 63-70 are drawn to the use of anti-CD2 antibodies, as exemplified by the MEDI-507 antibody, as well as other TNFα antagonists / anti-alphavbeta3 antagonists recited in the instant claims in addition to the product claims have been withdrawn from consideration as being drawn to non-elected inventions and species.

In response to applicant's inquiry, claims drawn to the use of TNF-alpha receptor / ENBREL / etanercept have been withdrawn from consideration as being drawn to non-elected inventions and species.

Therefore, claim 61 was inadvertently included in the rejections of record (e.g., compare to withdrawn claim 27 and the previous statements concerning the non-elected nature of the TNF-alpha antagonists in the previous Office Action, mailed 6/16/06 (e.g., see the previous rejection under 35 USC 112, second paragraph).

The examiner apologizes for any inconvenience to applicant in this matter.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.

This Action will be in response to applicant's amendment, filed 10/13/06.

The rejections of record can be found in previous Office Action, mailed 6/16/06.

3. In applicant's Remarks, applicant refers to paragraph numbers, however, the instant specification does not include paragraph numbers.

In the future, applicant should refer to the instant specification by page and paragraph / line numbering.

4. Claims 1-6, 9-11, 18, 22-24, 28-31, 43-52, 54, 58-60 and 62 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-6, 9-11, 18, 22-24, 28-31, 43-52, 54, 58-60 and 62 are indefinite in the recitation of "immunomodulatory agents", "anti-inflammatory agents", "immunomodulatory agents is a small organic molecule" because the claims do not apprise the ordinary artisan of the metes and bounds of each of these categories of therapeutic agents essentially for the reasons of record.

For example, there is overlap between "immunomodulatory agents" and "immunosuppressive agents".

Further, the claims have recited alphavbeta3 antagonists and TNF antagonists as separate categories, yet the ordinary artisan would ascribe both "immunomodualtory and immunosuppressive properties to such antagonists.

The term "immunodulatory" is relative in nature and does not apprise the ordinary artisan of the nature, direction or type of "modulation" encompassed by the claimed invention.

Applicant's arguments in conjunction with MPEP 2173.05(a), filed 10/13/06, have been fully considered but have not been found convincing essentially for the reasons of record.

While it is acknowledged that the instant specification (e.g., see page 29, paragraph 1 and pages 61-66 of the instant specification describes "immunodulatory agents" in the context of immusuppression and immunostimulatory activities,

applicant has not provided objective evidence that the phrase "immunomodulatory agents" was common terminology utilized by ordinary artisans in the art at the time the invention was made to the extent that it would have apprised the ordinary artisan of the metes and bounds of the claimed methods to ameliorate or treat inflammatory disorders or autoimmune disorders or one or more symptoms thereof as recited and encompassed by the instant claims.

For example Section 5.2.1 / Immumodulatory Agents of the instant specification can affect one or more or all aspects of the immune response in a subject and encompass proteinaceous agents, nucleic acid molecules, small molecules, organic compounds and inorganic molecules.

Given the diversity and breadth of the therapeutic endpoints as well as the diversity and breadth of the functional and structural aspects of the claimed "immunomodulatory agents",

the claimed "immunomodulatory agents" can essentially have any activity and any structure to the extent that the claimed "immunodmodulatory agents" do not reasonably apprise the ordinary artisan of the claimed invention, particularly as it reads on what appears to be overlapping categories of therapeutic molecules and activities encompassed by the claimed "immunodulatory agents".

Applicant arguments have not been found persuasive.

Again, applicant is invited to amend the claims to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Again, applicant is invited to recite specific "agents" or defined categories of agents that would reasonably apprise the ordinary artisan of the claimed invention, particularly as it reads on what appears to be overlapping categories of therapeutic molecules.

B) Claims 2, 4, 6, 9-11, 18, 22-24, 28-31, 43-54, 58-60 and 62 are indefinite in the recitation of "VITAXIN" and "REMICADE" and newly submitted "etaraizumab" and "infliximab" because their characteristics are not known. The use of "VITAXIN", "REMICADE", "etaraizumab" and "infliximab" as the sole means of identifying the claimed antibodies renders the claims indefinite because these are merely laboratory designations or non-proprietary names which do not clearly define the claimed products, since different laboratories may use the same laboratory designations / names to define completely distinct biological materials essentially for the reasons of record.

Amending the claims to recite the appropriate ATCC Accession Numbers would obviate this rejection.

Applicant's arguments in conjunction with MPEP 2173.05(a), filed 10/13/06, have been fully considered but have not been found convincing essentially for the reasons of record.

Applicant submits that the terms "VITAXIN" and "REMICADE" are definitive and well-defined in the art.

Applicant is reminded that the instant claims are drawn to biological materials.

As pointed out in the last Office Action, the use of "VITAXIN" and "REMICADE " and now newly submitted "etaracizumab" and "infliximab" antibodies as the sole means of identifying the claimed antibodies renders the claim indefinite because these "designations" are merely laboratory designations or non-proprietary names which do not clearly define the claimed products, since different laboratories may use the same laboratory designations /names to define completely distinct biological materials. There are many subjective and objective characteristics that can be associated with a biological materials such as an antibody, including the claimed antibodies. In addition, a particular biological material such as an antibody or a cell line / hybridoma which produce said antibody(ies) can undergo changes resulting in microheterogeneity.

While applicant relies upon the accepted recognition of the USAN (United States Adopted Name) Council to establish compliance with 35 U.S.C. § 112, second paragraph,

Applicant has not provided sufficient objective evidence to support this acceptance by the USAN or the ordinary artisan at the time the invention was made that the claimed terms defined one specific biological material / antibody, as asserted by applicant.

nor has applicant provided sufficient objective evidence that such terms are compliant with 35 U.S.C. § 112, second paragraph,

Applicant's arguments have not been found persuasive.

C) Claims 2, 4, 6, 9-11, 18, 22-24, 28-31, 43-54, 58-60 and 62 contain the trademark or trade name "VITAXIN", "REMICADE" (and non-elected "ENBREL" / "etancercept") and newly submitted "etaraizumab" and "infliximab". Where a trademark or trade name is used in a claims as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 USC 112, second paragraph, See Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademarks or the trade names are used to identify or describe "antibodies", and accordingly, the identification or the description is indefinite. The relationship between a trademark or tradename and the product it identifies may be uncertain and arbitrary. The formula or characteristics of the product may change from time to time and yet it may continue to be sold under the same trademark or trade name.

Applicant's arguments (in conjunction with MPEP 608.01(v)), filed 10/13/06, have been fully considered but have not been found convincing essentially for the reasons of record and addressed above.

It is noted that applicant acknowledges that the claimed terms are either trademarks or trade names.

While applicant relies upon the accepted recognition of the USAN (United States Adopted Name) Council to establish compliance with 35 U.S.C. § 112, second paragraph,

Applicant has not provided sufficient objective evidence to support this acceptance by the USAN or the ordinary artisan at the time the invention was made that the claimed terms defined one specific biological material / antibody, as asserted by applicant

nor has applicant provided sufficient objective evidence that such terms are compliant with 35 U.S.C. § 112, second paragraph,

Applicant's arguments have not been found persuasive.

D) Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

5. New Grounds of Rejection.

Claims 2, 4, 6, 9-11, 18, 22-24, 28-31, 43-54, 58-60 and 62 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

The specification as originally filed does not provide support for the invention as now claimed:

"etaracizumab" and "infliximab" (and non-elected "etanercept").

While applicant relies upon the accepted recognition of the USAN (United States Adopted Name) Council to establish compliance with 35 U.S.C. § 112, first and second paragraphs, addressed herein in this Office Action,

applicant has not provided sufficient objective evidence to support this acceptance by the USAN or the ordinary artisan at the time the invention was made that the claimed terms defined one specific biological material / antibody, as asserted by applicant

nor has applicant provided sufficient objective evidence that such terms are compliant with 35 U.S.C. § 112, first paragraph, with respect to adding material to an application subsequent to filing.

However, the recitation of "etaracizumab" and "infliximab" (and non-elected "etanercept") is not readily apparent either in the pending or priority applications.

The instant claims now recite limitations which were not clearly disclosed in the priority applications as well as the specification as-filed, and would have changed the scope of the priority applications and do change the scope of the instant disclosure as-filed.

Also, it is noted that entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977).

The specification as filed does not provide a sufficient written description of "etaracizumab" and "infliximab" (and non-elected "etanercept"). The specification does not provide blazemarks nor direction for the instant methods encompassing the above-mentioned "limitations" as currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and may change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Again, see applicant's arguments and the examiner's rebuttal with respect to "etaracizumab" and "infliximab" (and non-elected "etanercept") under 35 USC 112, first and second paragraphs, herein.

Also, note that applicant has not pointed to sufficient antecedent basis to the specification as filed for the recitation of "etaracizumab" and "infliximab" (and non-elected "etanercept").

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above.
See MPEP 714.02 and 2163.06

6. Claims 2, 4, 6, 9-11, 18, 22-24, 28-31, 43-46-54 and 58-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

It is apparent that the "VITAXIN" and "REMICADE" and newly submitted "etaracizumab" and "infliximab" antibodies are required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the pertinent cell lines / hybridomas which produce these antibodies. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

Applicant's arguments in conjunction with MPEP 2404(b) and 608.01(v), filed 10/13/06, have been fully considered but have not been found convincing essentially for the reasons of record.

However, biological materials must be known and readily available to the public (See MPEP 2404.01). Neither concept alone is sufficient. The fact that applicant and other members of the public were able to obtain the materials in question or that they were well-defined in the literature prior to and after the filing date of the application does not establish the upon issuance of a patent on the application that such material would continue to be accessible to the public. The applicant did not make of record any of the facts and circumstances surrounding the access to the biological materials, nor is there any evidence as to the policies regarding the materials if a patent would be granted. Further, there are no assurances that those entities in control of the claimed biological materials would allow unlimited access to the biological materials if the instant application would mature into a patent.

In the absence of evidence that the "VITAXIN" and "REMICADE" and newly submitted "etaracizumab" and "infliximab" antibodies are readily available to the public and that all restrictions imposed by the owner / depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, applicant's arguments have not been found persuasive and the rejection is maintained.

Again, applicant is invited to clarify the record for the public availability of the claimed "VITAXIN" / "REMICADE" and newly submitted "etaraizumab" and "infliximab" antibodies with respect to the requirements for the deposit of biological materials under 35 USC 112, first paragraph. See MPEP 2400.

9. Claims 1-6, 9-11, 18, 22-24, 28-31, 43-52, 54 and 58-62 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Feldman et al. (U.S. Patent NO. 6,270,766) in view of by Huse (U.S. Patent No. 6,596,850), The Merck Manual of Diagnosis and Therapy, Seventeenth Edition, edited by Beers et al., Merck Research Laboratories, Whitehouse Station, NJ, 1999 (see pages 416-423) and Strom et al. (in Therapeutic Immunology edited by Austen et al., Blackwell Science, Cambridge, MA, 1996; see pages 451-456) essentially for the reasons of record.

Applicant's arguments in conjunction with MPEP 2143, filed 10/13/06, have been fully considered but have not been found convincing essentially for the reasons of record.

Applicant submits that the there is no motivation in the prior art to modify or to combine specific treatment regimes to meet the claimed methods.

With respect to the teachings of Feldman et al.,

applicant asserts that Feldmann et al. is limited to immunosuppression and does not provide for scenarios that would require immunostimulation with a combination therapy.

Here, it appears that applicant is arguing limitations not claimed, nor consistent with the elected invention.

In addition, applicant asserts that Feldmann et al. also does not teach nor suggest the one could target adhesion molecules, such as the targeted integrins in therapeutic methods.

One cannot show non-obviousness by attacking references individually where the rejections are based on a combination of references. See In re Young, 150 USPQ 725 (CCPA 1968). See MPEP 2145.

Further, it is noted that Feldmann et al. does describe that other therapeutic regimens and agents can be used in combination with the therapeutic administration of TNF antagonists or other drugs that suppress the immune system (e.g., see Detailed Description of the Invention, particularly, column 4, paragraph 5).

Also, applicant's assertions are inconsistent with the disclosure of the instant specification, which acknowledges that any immunomodulatory agent well-known to one of skill in the art may be use in the methods of the invention (e.g., see page 61, paragraph 1).

In a similar fashion, applicant's arguments and the examiner's rebuttal with respect to applicant's assertions that Huse does not teach the claimed combination of therapies or the specific immunomodulatory agents are essentially the same addressed above with respect to the teachings of Feldmann et al.

Also, consistent with the teachings of Feldmann et al. and the disclosure of the instant specification as-filed, Huse does teach that Vitxain/LM609-specific antibodies can be administered with other compositions which can inhibit enhance or supplement the treatment or reduction in the severity of an αvβ3-mediated disease (e.g., see Detailed Description of the Invention, particularly column 26, paragraph 2).

Applicant assert that at the time of filing, no reasonable expectation of success for the teachings of claimed invention were evident from the cited references.

However, applicant does not provide sufficient objective evidence to support the assertions of non-obviousness.

As indicated herein, once a prima facie case of obviousness has been made the burden of going further is shifted to applicant. See In re Keller, 208 USPQ 871, 882 (CCPA 1981). This applicant has not done, but rather merely asserts that the prior art does not provide sufficient suggestion or motivation to combine the prior art to treat inflammatory disorders / autoimmune diseases, including rheumatoid arthritis, with the combination of TNFα antagonists such as anti-TNFα antibodies and alphavbeta3 antagonists such as LM609/Vitaxin-specific antibodies and does not address the teachings of the references individually and not their teachings individually or in combination. Also, as noted herein, applicant's arguments are inconsistent with applicant's arguments in addressing the rejections under 35 USC 112, first and second, paragraphs, wherein applicant appears to acknowledge the well known use and characteristics of TNFα antagonists such as the anti-TNFα antibody infliximab and alphavbeta3 antagonists such as the humanized LM609/Vitaxin- antibody at the time the invention was made.

One cannot show non-obviousness by merely asserting that the references do not provide the sufficient elements of obviousness or by attacking references individually where the rejections are based on a combination of references. In re Young 403 F.2d 759, 150 USPQ 725 (CCPA 1968). See MPEP 2145.

When considering the disclosure of a reference, it is proper to take into account not only specific teaching of the reference but also the inferences which one skilled in the art would be reasonably be expected to draw therefrom In re Preda, 401 F.2d 825, 159 USPQ 342, 344 (CCPA 1968). See MPEP 2144.01

Specific statements in the references themselves which would spell out the claimed invention are not necessary to show obviousness, since questions of obviousness involves not only what references expressly teach, but what they would collectively suggest to one of ordinary skill in the art. See CTS Corp. v. Electro Materials Corp. of America 202 USPQ 22 (DC SNY); and In re Burckel 201 USPQ 67 (CCPA).

Further, in response to applicant's arguments that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine 5 USPQ2d 1596 (Fed. Cir 1988) and In re Jones 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, the teachings of combined references pertaining to the ability to inhibit rheumatoid arthritis with either TNFα antagonists such as anti-TNFα antibodies or alphavbeta3 antagonists such as LM609/Vitaxin-specific antibodies, including combination therapies, which encompassed conventional practices at the time the invention was made, would have led one of ordinary skill in the art at the time the invention was made to combine the references to address similar and well known therapeutic endpoints associated with ameliorating or treating inflammatory disorders / autoimmune diseases, including rheumatoid arthritis with an expectation of success in the absence of objective evidence to the contrary.

Given the combined teachings, one of ordinary skill in the art at the time the invention was made would have been motivated and would have had a reasonable expectation of success of providing multiple immunosuppressive agents in the treatment of rheumatoid arthritis, as commonly practiced at the time the invention was made, and as taught by the primary and secondary references. Also, it is noted that the teachings of both Feldman et al. and Huse are consistent with this common practice, as both teachings teach combination therapies with either TNFα antagonists such as anti-TNFα antibodies or alphavbeta3 antagonists such as anti-alphavbeta3 antibodies, including their combination with known therapeutic regimens for the disease targeted.

Also, it was prima facie obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. In re Kerkhoven, 205 USPQ 1069, CCPA 1980. See MPEP 2144.06.

It appears that the claimed limitations were well within the purview of an ordinary artisan at the time the invention was made. The various dosages and modes of administration encompassed by the claimed methods (e.g. see claims 31, 50-54 and 59-62) appear to the same or nearly the same as set above, particularly in the teachings of Feldman et al. (e.g. see Administration on column 18, to meet the needs of the patient and the particular disease. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention

The strongest rationale for combining reference is a recognition, expressly or implicitly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent that some advantage or expected beneficial result would have been produced by their combination In re Sernaker 17 USPQ 1, 5-6 (Fed. Cir. 1983). See MPEP 2144.

There is no requirement under obviousness that the prior art contain an express suggestion to combine the known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art.

See Motorola, Inc. v. Interdigital Tech. Corp., 43 USPQ2d 1481, 1489, (Fed. Cir. 1997).

Applicant's arguments have not been found persuasive.

10. No claim is allowed.

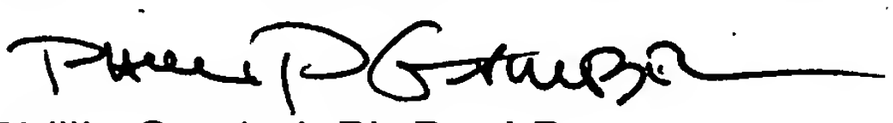
11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Phillip Gambel, Ph.D., J.D.
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December 26, 2006